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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09 730,542      | 12 07 2000  | Sung Kyu Ji          | 0655-0114P          | 9346             |

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EXAMINER

WEBER, JON P

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1651

DATE MAILED: 05/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/730,542

Applicant(s)

JI, SUNG KYU

Examiner

Jon P Weber, Ph.D.

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 19 March 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 7-9 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3 is/are rejected.
- 7) ☒ Claim(s) 7-9 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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*Status of the Claims*

The response with amendments filed 19 March 2003 has been received and entered. Claims 1-3 and 7-9 have been presented for examination.

*Claim Rejections - 35 USC § 102*

Claims 1 and 3 stand rejected under 35 U.S.C. 102(b) as being anticipated by newly cited Jensen (US 3,969,540).

It is argued that the incomplete digestion method of Jensen produces polypeptides that are distinct from the instant oligopeptides. It is urged that the reaction times in Jensen, 2 hours to 5 days, are much broader than instantly, 10-12 hours. It is argued that Jensen use various metal salts to precipitate the polypeptides whereas the instant zinc-oligopeptides are soluble. Hence, it is urged that the instant method produces a different product.

The terms polypeptides and oligopeptides are overlapping in peptide length. The dictionary indicates that poly can be used when there are more than three monomers, and that the term oligo is generally reserved for small numbers of monomers of less than twenty. Jensen is vague about the length of the polypeptides produced. The intention was to provide incomplete hydrolysis solely to prevent formation of amino acids. The length of incubation time depends on several factors: quantity of material being processed, the ease of hydrolysis, the extent of hydrolysis desired, the specific proteases used, the pH, and the temperature for example. A person of ordinary skill in the art understands that these result effective parameters are routinely varied. The instant claims do not reflect a period of incubation, precisely because it was not desired to be limited by time when the incubation time is affected by so many other variables.

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There is a wealth of experience in the art of protein digestion by proteases. By varying the known parameters, a skilled artisan is able to obtain desired degrees of digestion. The instant claims only vaguely refer to oligopeptides. There is no evidence that **only** oligopeptides are produced by the claimed process. Only that oligopeptides are produced. Given the teachings in Jensen, it is asserted that oligopeptides are indeed produced.

The specific examples in Jensen previously noted precipitate the peptides with zinc. The argument with respect to metal cations in general is not understood.

The argument that the instant zinc-peptide species are soluble is not in evidence in the claims. Further, it is known in the art that the solubility of complexes this nature is pH dependent. That is, Jensen takes advantage of the insolubility of the complex to concentrate the material by precipitation before drying to a powder.

In conclusion, the method of Jensen produces a product within the scope of the instant claims.

Applicant's arguments filed 19 March 2003 have been fully considered but they are not persuasive. The rejection under 35 U.S.C. 102(b) is adhered to for the reasons of record and the additional reasons above.

### ***Claim Rejections - 35 USC § 103***

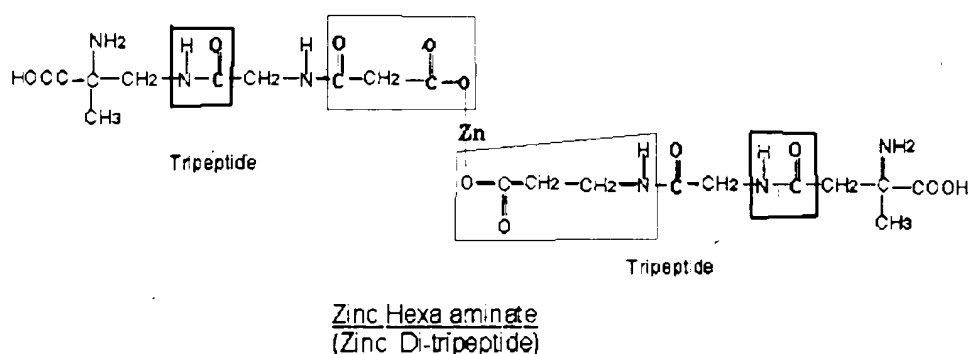
Claims 1-3 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Ashmead (US 4,172,072).

It is argued that the tripeptide of Ashmead is an aminate that ionizes in solution and cannot chelate zinc in the claimed manner. It is argued that some amino acids interact and some

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don't with mineral ions. It is urged that carboxyl radicals or amino groups at  $\alpha$ -carbons do not react with mineral acids, but participate only in formation of peptides. It is argued that it is improper for the Office to assume that all dipeptides and tripeptides participate in formation of an aminate structure.

Consider the "amine" structure set forth at page 6 of the response of 17 Oct 2002.



For convenience of discussion several elements have been highlighted. In both "tripeptides" the heavy box surrounds a non-natural peptide bond using the side chain amino on the first "tripeptide" and the side chain carboxyl from the second "tripeptide". The lighter boxes surround, in the first "tripeptide" the compound malate, which is not an amino acid, and in the second "tripeptide", 3-aminopropanoate, which is not an  $\alpha$ -amino acid. Hence, neither of these is a tripeptide as argued in the Office action. A proper tripeptide can readily be envisaged from the structure of instant Figure 1, if the peptide bond between Lys and Ala were replaced with the respective free amino and carboxyl groups. If this were done, it would not affect the chelating ability of the side chain groups depicted in the figure (all four points of chelation with the peptide are shown through the side chains). There is clearly an additional point of ionization at the new termini for each of the tripeptides. However, the presence of these groups does not

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appear to impair the chelating ability of the side chains. The response does not provide evidence to support the assertion that two small peptides could not chelate the zinc. The chemistry of inorganic ion chelates is well-studied. There are numerous examples of chelating agents that have a ratio of 2:1 agent to metal ratio. The claims rejected do not require any particular structure, just chelation. There is no particular sequence requirement.

Applicant's arguments filed 19 March 2003 have been fully considered but they are not persuasive. The rejection under 35 U.S.C. 103(a) is adhered to for the reasons of record and the additional reasons above.

***Allowable Subject Matter***

Claims 7-9 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

No claims are allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

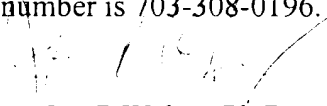
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will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon P Weber, Ph.D. whose telephone number is 703-308-4015. The examiner can normally be reached on daily, off 1st Fri, 9/5/4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 703-308-4743. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

  
Jon P Weber, Ph.D.  
Primary Examiner  
Art Unit 1651

JPW  
May 22, 2003